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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,512	05/05/2000	MICHAEL ANTHONY JOHNSON	2-00US	2004

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EXAMINER
WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 01/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/485,512	JOHNSON ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *3,5-24,33-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4, 25-32, 39-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election with traverse of group I in Paper No. 14 is acknowledged. The traversal is on the grounds that this is a 371 application and there was no lack of unity held in the PCT processing, that other application/patents which have been presented to the office did not hold such requirements (see Pat No. 6296852) and that the claims should be examined together because they are all dependent on claim 1. This is not found persuasive because the PCT examining criteria and the criteria for examining 371 applications are not identical. 37 CFR 1.475 sets out the criteria if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c). Here the main invention has been found to be a product the recombinant porcine adenovirus with an inserted DNA of interest, a method of making the recombinant adenovirus and a method of using the recombinant adenovirus. The group II is a product wherein the adenovirus contains more than one heterologous sequence (protein of interest + immunomodulating molecule) while group III is drawn to a method of immunomodulating using the recombinant virus. The search for group I will not be coextensive with group II which contains multiple heterologous sequences or group III and thereby each group requires additional searching in the database.

The requirement is still deemed proper and is therefore made FINAL. Claims 1, 2, 4, 25-32 and 39-42 are under consideration in the instant office action. Claims 3, 5-24 and 33-38 are drawn to a non-elected invention and are thereby withdrawn from consideration.

Specification

Applicant is required to update the status (pending, allowed, ect.) of all parent priority applications in the first line of the specification.

The disclosure is objected to because of the following informalities: The margins for Table 2 on page 15 are too close to the edge of the paper, in the process of organizing the papers into the file wrapper, holes were punched into the table deleting data numbers from the table. Appropriate correction is required.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 6, is attached to the instant Office action. The references have been considered only to the level provided in the English abstract in the case of WO 95/0269 and the English abstract and excerpts in the case of WO 97/20036.

Drawings

The drawings are objected to, please see Notice of Draftsperson's Review attached to the instant Office Action. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31, 32 and 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what is meant by "at least one heterologous nucleotide sequence". The ordinary artisan can interpret this to mean multiple sequences encoding separate proteins or a single sequence encoding a protein and heterologous promoter. For example the SV40 promoter driving the expression of the gpS gene of a porcine respiratory coronavirus (see below). Therefore, it is not clear what is meant by "at least one heterologous nucleotide sequence" in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 25-32 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Callebrant et al. (Cornaviruses 1994,see IDS paper No. 6) or Torres et al. (Journal of Virology 1996, see IDS paper No. 6) and either Kleiboeker (Virus Research, 1994, see IDS paper No. 6) or Reddy et al. (Virus Research 1996, see IDS paper No. 6).

The instant invention is drawn to a porcine adenovirus vector that is capable of expressing a heterologous protein sequence. Additionally, the recombinant virus may be used as a live vaccine vector.

Callebrant et al. teach the use of a recombinant human adenoviral vector which is used as a vaccine for porcine respiratory coronavirus. The gpS gene of porcine respiratory coronavirus was positioned in the deleted E3 region of the human Ad5 adenovirus. Expression of the gpS gene is driven by the SV40 promoter and the heterologous sequence also contains SV40 polyadenlyation signal, indicating that this sequence comprises more than one heterologous sequence. The E3 region has been found not to be required for replicating adenovirus in tissue culture, the gene may be deleted or a gene may be inserted into this region without effecting replication. The reference teaches the need for the devolvement of vaccine for the protection of farm animals (pigs) from respiratory and enteric disease. The reference does not teach the production of a recombinant porcine adenoviral vector for the use as a vaccine in pigs.

Torres et al. teach a recombinant human adenoviral vector, which is used as a vaccine for transmissible gastroenteritis coronavirus (see discussion). The human adenoviruses have a restricted host range, the infection of cells from other species results in the production of low or no virus production. The reference teaches Ad5 can replicate in porcine cells and that these cells supported the expression of heterologous sequences when they were inserted into the E3 region

of the adenovirus. The adenoviral vector was shown to be effective as a live vaccine in pigs. The reference does not teach the use of a porcine adenoviral vector.

Keliboeker et al. teach the sequence analysis of the porcine adenoviral E3 region (see figure 2). The E3 region shares common location and size to the E3 region of other adenoviruses (see last paragraph). The E3 region has been used in other adenoviruses for the insertion of heterologous sequences for protein expression *in vivo* and *in vitro*. The E3 region may be suitable for the insertion of heterologous genes in an effort to produce a viral vaccine in this particular host species.

Reddy et al. teach the sequencing and sequence similarities of three porcine adenoviruses E3 regions. There is interest to develop these vectors as a vaccine for the mucosal immune response in pigs against enteric disease. The reference suggests using these adenoviruses as expression vectors for foreign genes in pigs.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to develop a porcine adenoviral vector, as suggested by either Kleiboeker or Reddy et al. for the expression of foreign genes to be used as a vaccine in swine. One having ordinary skill in the art would have been motivated to do this because the species-specific adenovirus will replicate at higher efficiency in the host resulting a better vaccine. Several serotypes of human adenoviruses were shown to replicate in cells of animal origin. Therefore, it is highly likely that these human adenoviruses viruses would cross species barriers when used in field conditions as animal vaccines, i.e. the virus replicates in the animal picks up other genes and then enters the human host again these additional genes may cause severe reaction in the human host. Animal adenoviruses are very species specific, they can enter human cells but do not replicate. One

having ordinary skill in the art would be motivated to develop an efficient vaccine for the swine diseases discussed by either Callebrant et al. or Torres et al. in order to minimize the financial burden in the pork industry caused by such viral disease. Given the broad general knowledge in the art for the production of recombinant adenoviral vectors by inserting the genes into the E3 region and other regions are also known in the art to support insertions, in combination with the clear suggestion to develop porcine adenoviral vectors including making the insertions into the E3 region. Therefore, the instant invention is obvious in view of the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

JEFFREY STUCKER
PRIMARY EXAMINER